Attachment 3

K071165

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510(k) Summary

Submitter: Alertis Medical ASA
Oslo, Norway

Contact Information: Constance G. Bundy
C. G. Bundy Associates, Inc.
6470 Riverview Terrace
Fridley, MN 55432

NOV 07 2007

Submission Date: April 24, 2007

Device Name: IscAlert™ Sensor System

Classification: Class II, 21 CFR 882.1620, Code: GWM

Equivalent Device Identification: The IscAlert Sensor System is substantially equivalent in function to the Neurotrend™ Cerebral Tissue Monitoring System (K980308). The IscAlert sensing technology is substantially equivalent to the Paratrend 7™ Intravascular Blood Gas Monitoring System (K953893). The company provided performance data demonstrating the safety and efficacy of the Sensor System for the intended use of measurement of the partial pressure of carbon dioxide in peripheral tissue, such as the forearm muscle tissue.

Device Description: The IscAlert sensor system measures partial pressure of CO_2 (pCO_2) in peripheral tissue, such as forearm muscle tissue, where the sensor is inserted. The system is intended to monitor pCO_2 trends as an adjunct in the evaluation of perfusion status of tissue in patients at risk of developing ischemia.
Ischemia is a medical term for a shortage of blood supply to tissue. If severe, it can lead to death of the affected tissue (infarction). The tissue pCO_2 increases significantly during the early and reversible stages of ischemia. This methodology provides the ability to identify the onset of ischemia events through real-time data.

The IscAlert sensor system consists of three parts:

1. The sterile disposable Sensors
2. The Connection Unit (CU)
3. Software to be installed in an off-the-shelf PC unit

The sterile, disposable, catheter tip sensors are placed 2-5 cm into organ tissue with a split-off needle that is removed after insertion.
The sensor is connected via a cable to the Connection Unit (CU). The CU processes the signals from the sensor unit. It is connected via a cable to a PC with the IscAlert software application installed. The software enables visualisation of the monitoring results.

Intended Use: The IscAlert™ sensor system measures partial pressure of carbon dioxide in peripheral tissue, such as forearm muscle tissue, where the sensor is inserted. The system is intended for monitoring trends in this parameter as an adjunct in the evaluation of the perfusion status of tissue in patients at risk of developing ischemia. IscAlert values are relative within an individual and should not be used as the sole basis for decisions as to diagnosis or therapy. The IscAlert™ sensor system should not be used in peripheral brain tissue, intra cranial tissue, all organ tissues including cardiac and kidney, and other peripheral muscle tissues other than forearm muscle.

Substantial Equivalence: The IscAlert Sensor System is similar in function to the Neurotrend Cerebral Tissue Monitoring System (K980380). The IscAlert and Neurotrend devices measure pCO_2 in peripheral tissue and monitor trends in this parameter as an adjunct for managing patients at risk for ischemia. The IscAlert sensing technology is equivalent to the sensing technology of the Paratrend device. Both devices utilize electrochemical sensors to measure partial gas pressure. Alertis Medical believes the IscAlert to be substantially equivalent to device technology currently available and the device raises no new issues of safety when compared to the predicate devices. The company provided performance data to demonstrate the safety and efficacy of the Sensor System for the intended use.

Summary of Testing: The IscAlert Sensor System has been tested for function according to the product requirements. The System has also been tested for EMC and safety requirements. The results of these tests and a proof-of-concept clinical study using Neurotrend as comparative device show the IscAlert Sensor System to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alertis Medical AS
% C.G. Bundy Associates, Inc.
Ms. Constance G. Bundy
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Fridley, Minnesota 55432

NOV 07 2007

Re: K071165
Trade/Device Name: IscAlert™ Sensor System
Regulation Number: 21 CFR 868.1150
Regulation Name: Indwelling blood carbon dioxide partial pressure (P_{co2}) analyzer
Regulatory Class: II
Product Code: CCC
Dated: October 13, 2007
Received: October 17, 2007

Dear Ms. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 4 K071165

Indications for Use

510(k) Number (if known): K071165

Device Name: IscAlert™ Sensor System

Indications For Use:

The IscAlert™ sensor system measures the partial pressure of carbon dioxide in peripheral tissue, such as forearm muscle tissue, where the sensor is inserted. The system is intended for monitoring trends in this parameter as an adjunct in the evaluation of the perfusion status of tissue in patients at risk of developing ischemia. IscAlert values are relative within an individual and should not be used as the sole basis for decisions as to diagnosis or therapy.
The IscAlert™ sensor system should not be used in peripheral brain tissue, intra cranial tissue, all organ tissues including cardiac and kidney, and other peripheral muscle tissues other than forearm muscle.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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